EXHIBIT E

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE l OF MDL 200:	Master File No. 2:ll-MD-02327
	MDL 2327
Joan Adams v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-1103	
Lois Hoy, et al v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00876	
Charlene Miracle v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00510	
Donna Zoltowski, et al. v. Ethicon, Inc., et al. Civil Action No. 2:12-cv-00811	

DEPOSITION OF

RUSSELL F. DUNN, PH.D., P.E.

Taken on behalf of the Defendants

March 7, 2016

RUSSELL F. DUNN, PH.D., P.E.

was called as a witness, and after having been first duly sworn, testified as follows:

EXAMINATION BY MR. DAVIS:

Q. Good morning, Dr. Dunn.

A. Good morning.

Q. Since we've met before, I'll just kind of jump into things. Let me hand you first, to start off, a copy of Exhibit 1.

(Whereupon Exhibit 1 was marked as an exhibit.)

BY MR. DAVIS:

Q. And can you just confirm that that's a copy of your report that is the subject matter of this deposition?

A. Yes, sir.

Q. Okay. Let me just run through a couple more documents.

Well, why don't you just keep -- yeah, we'll --

A. Oh. Sure.

Q. I realize you've got your own notebook with your copy.

A. Uh-huh.

configuration.

BY MR. DAVIS:

Q. Okay. Can you explain how Prolift+M differs from Prosima?

MR. BOWMAN: Object to the form.

BY MR. DAVIS:

Q. And if it's the same answer, that's fine.

A. Oh, the Prolift+M has Monocryl filament in it, also, in addition to the polypropylene.

Q. And what is the significance of the Monocryl?

A. It's biodegradable.

Q. Okay. As I read your report, I -- I see a number of references to ISO 14971.

Do you recall that?

A. Yes, sir.

Q. And were there any other medical industry specific standards that you relied upon in your report other than ISO 14971?

A. I specifically dealt with the ISO 14971 and insofar as it references other standards that it relies upon.

Q. Okay. Well, are you aware that ISO 14971 does cite a number of other standards?

A. Absolutely, I'm aware of that.

Q. And I'm just trying to understand. Did you go -- did you have any occasion to go review any of those other standards that are cited in ISO 14971?

A. I may have reviewed some of those standards. Not -- they were not the subject of my report. I specifically dealt with 14971.

Q. Okay. And let me just follow up.

You may or may not recall that, at your last deposition, I asked you some questions about ISO 10993 and its various subparts.

Do you recall that generally?

A. Yes. Biocompatibility, yes, sir.

Q. Have you had any occasion since your last deposition to review any portions of ISO 10993?

A. That's -- no, sir. That's not my area of expertise, is biocompatibility.

Q. Okay. Do you -- do you know what all the subject matter of biocompatibility encompasses?

MR. BOWMAN: Object to form.

BY MR. DAVIS:

Q. Well, I mean, I understand it's not your expertise.

MR. BOWMAN: Object to form.

BY MR. DAVIS:

Q. Do you have an opinion as to how long Prolene mesh needs to be in the body before it doesn't matter whether it has some degradation?

MR. BOWMAN: Object to form.

THE WITNESS: That's not the subject of my report.

BY MR. DAVIS:

Q. Do you know of any harm associated with the oxidative degradation of Prolene used in the pelvic floor?

A. All I know is how the properties of the polymer change. And that's the subject of my report. And that it gets hard and embrittled as it oxidizes.

Q. Well, but the subject of your report is also FMEAs and risk analysis, right?

A. It is FMEAs.

Q. And you understand that, in order to call something a hazard, which you've done -- well, let's back up.

You -- throughout your report, you call Prolene mesh in the body a hazard, correct?

A. I say that it should be evaluated for

potential failure modes.

Q. Well, now, let me ask you. I mean -- well, you agree your report repeatedly says that Prolene used in a mesh in the pelvic floor is a hazard?

A. It readily oxidizes, yes. And that's -- and that is a defect.

Q. But your opinion is that it is a hazard, correct?

A. Yes.

Q. Okay. And you understand -- according to ISO 14971, you understand the definition of a hazard, correct?

A. Yes.

Q. What is that definition?

A. A potential source of harm.

Q. Okay. So please identify the harm that you have associated with oxidative degradation of polypropylene in order to allow you to call it a hazard.

A. You're -- I'm telling you that it gets hard and it gets embrittled, and I'm also indicating that, as a potential failure mode, it has to be fully evaluated by Ethicon relative to its harm.

Q. As -- as you sit here today, do you know of any harm that you can tell the Court that's associated with what you describe as Prolene being a hazard?

A. I know the changes in the polymer itself, that it becomes cracked and embrittled and hard.

Q. Okay. My question is, can you -- can you identify any specific harm today?

A. That it's changing the properties inside the body over time.

Q. Do you understand the definition of "harm"? What does "harm" mean?

MR. BOWMAN: Object to form.

THE WITNESS: Physical injury or damage to the health of people or damage to the property or the environment.

BY MR. DAVIS:

Q. Okay. Can you tell me any injury to the person in whom the mesh is implanted?

A. That's not the subject of my report.

Q. Okay. Yet -- so you've -- you've labeled Prolene mesh in the pelvic floor as a hazard, but you have not been able to associate that hazard with any specific harm?

it works, and then I'll hand it over.

MR. DAVIS: Okay.

BY MR. DAVIS:

Q. In the meantime, Dr. Dunn, I've handed you Exhibit 6, and my first question is, can you tell us whether this is a document that you considered as part of your analysis?

A. It could be. I don't know.

Q. Well --

A. I don't have every document memorized.

Q. Okay.

A. And I've looked at documents over the last two years.

Q. Okay. Let me put it this way: In your report, at various points you say that it's your opinion that Ethicon failed to consider oxidative degradation, correct?

A. That is correct.

Q. So did -- if -- did you make any effort to look at Exhibit Number 6 and -- and distinguish it or to justify an opinion that we're not considering oxidative degradation?

A. I am justifying that opinion based on the failure mode and effects analysis. This is not the failure mode and effects analysis. If they

considered oxidative degradation, it will be in their failure mode effects and analysis.

If you want to show me a failure mode and effects analysis that has a line item of oxidative degradation, then they considered it. Otherwise, they did not consider it. If it's not in the FMEA, it was not considered.

Q. Okay. So -- have you ever heard of a biocompatibility risk assessment?

A. Not a specific biocompatibility risk assessment. The ISO 10- -- 14971 includes biocompatibility. It considers that -- it's inclusive of that in the risk assessment.

Q. Okay.

A. You don't have separate risk assessments for different matters. When we talk about the overall risk assessment of a product, it all has to be within ISO 14971.

(Whereupon Exhibit 7 was marked as an exhibit.)

BY MR. DAVIS:

Q. Let me hand you Exhibit 7.

A. Yes, sir.

Q. Do you see the first page of this exhibit has a title "Essential Requirements

oxidative degradation of Prolene in the pelvic mesh, once it's in the body, has any practical consequence?

A. I don't know what Ethicon's evaluation of that was because it was not included in their FMEA. You're asking me to do what they should have done, and I'm telling you that I want to look at how they view that and how they judge that risk, and it's not part of their analysis.

Q. I hear you. But --

A. It's absent.

Q. Yeah. And -- I hear you. But now -- listen very carefully to my question.

A. Yes.

Q. I just want a "yes" or "no," and then you can explain.

Do you know whether there is any practical consequence to oxidative degradation of Prolene in the Prolene meshes that are the subject of your report once they're in the body?

A. That's -- that's not part of my report. I know the consequences on the polymer properties itself, and I've not extended that to the effect in the human body.

Q. So is the answer to my question "yes"

Q. Okay. And so it says in Section 4.1, the first sentence, quote, Risk analysis shall be performed for the particular medical device as described in 4.2 to 4.4, unquote.

Did I read that correctly?

A. Yes.

Q. Okay. And notice that, under that Section 4.1, it has a series of notes.

Do you see that series of notes?

A. Yes.

Q. Notes 1 through 4 and --

A. Yes.

Q. Look at Note Number 4. Do you see it says, quote, Additional guidance on risk analysis techniques for toxicological hazards is given in Annex I, unquote.

A. Sure.

Q. Did I read that correctly?

A. Yes.

Q. Okay. So you're familiar with Annex I?

A. I've seen Annex I, sure.

Q. Okay. And so -- you've turned to Annex I?

A. Yes.

Q. Do you see it has a title, "Guidance on

Risk Analysis Process for Biological Hazards"? That's the title?

A. Yes.

Q. Okay. And then what standard does it cite the reader to for the general principles for the biological evaluation of materials and medical devices?

A. For biological hazards, it's 10993, as I indicated previously.

Q. Well, it didn't say biological hazard; it says "biological evaluation," doesn't it?

A. That -- that sentence says that. But it's under Annex I, which is the guidance on risk analysis process for biological hazards.

Q. Okay. You don't think it has anything to do with chemical hazards?

A. I -- let's address that. Go back to Table E.1, page 51.

Q. Sure.

A. I specifically indicated that those are examples of hazards. You should see in the second column there is a heading called "Biological." It is not the same heading as "Chemical."

I told you before that degradation products is under chemical; it's not under

biological, nor is it under biocompatibility.

So let's don't confuse the two.

Q. So what standard does the ISO refer you to -- to -- for guidance on chemical hazards?

A. There -- there isn't one. You need chemical expertise. You need polymer expertise. There's no one standard for chemical analysis.

Q. Okay. Let's turn back to Annex I for a second.

A. Okay. I'm there.

Q. Look at Section 1.2.1. And do you see where that section reads in part, quote, The biological risk analysis should take account of, and then it lists four bullet points, correct?

A. Uh-huh.

Q. The first bullet point is "The physical and chemical characteristics of the various choices of materials."

Do you see that?

A. Yes.

Q. And do you see on down in Section 1.2.2, it specifically includes, among the analysis of biocompatibility, the influence of biodegradation, correct?

A. It does.

Q. Okay. So will you now agree that ISO 10993 does, in fact, address such matters as how you do a risk analysis to look at oxidative degradation?

A. I will not.

Q. Okay. So --

A. And I disagree totally.

Q. Okay. So your opinion is that Annex I has nothing to do with analyzing oxidative degradation?

A. I'm saying -- I'm saying that Annex I does not necessarily include oxidative degradation. It is more -- more concerned with biocompatibility and toxicity of chemical constituents and those types of matters.

Q. Okay. Well, what does it mean when it says -- when it says in 1.2.2, your risk analysis should include the, quote, chemical nature of the materials, unquote?

A. Where -- where are you?

Q. Look at the heading for Section 1.2.2, "Chemical Nature of the Materials."

Is it your testimony that you don't think that includes the possibility of oxidative degradation?

A. The intent is to say that they -- that Ethicon has not performed a risk analysis on oxidative degradation.

Q. Yeah. And so let me ask you this. Look on down to the third paragraph on that page.

A. Uh-huh.

Q. The second sentence. Says, quote, An important consideration in the acceptability of a residual risk is whether an anticipated clinical benefit can be achieved through the use of alternative design solutions or therapeutic options that avoid exposure to that risk or reduce the overall risk, unquote.

Did I read that correctly?

A. Yes.

Q. Okay. And, again, I just want to make sure I've covered this -- well, first, do you agree that that is an important consideration?

A. Yes.

Q. Okay. And have you considered that in any of your work on this case?

A. That's not what I'm doing. I'm assessing whether or not Ethicon has performed a risk/benefit analysis.

Q. Okay.

A. And the problem is -- and you're not asking me this question -- and I know why -- Ethicon can't do a risk/benefit analysis because they haven't evaluated the risk. So it's kind of hard to do a risk/benefit analysis when you don't evaluate the risk first.

Q. Okay.

A. And my assessment is to look at what Ethicon has done, not to perform that for them.

Q. Okay. Thank you.

Turn on page 39 of ISO 14971.

A. Yes.

Q. Do you see they have a section on "Risk Evaluation and Risk Acceptability"?

A. Yes.

Q. Are you familiar with that section?

A. Yes.

Q. Okay. So you do -- you do understand that one important consideration when you're evaluating risk is to have an understanding of what the state of the art is?

A. Yes.

Q. Okay.

A. Yes.

Q. And, again, you don't have an

understanding of what the state of the art is for these pelvic floor mesh devices, do you?

MR. BOWMAN: Object to form.

THE WITNESS: That's not the purpose of -- of my report.

BY MR. DAVIS:

Q. Well, so do you or don't you?

A. I understand different methodologies, but that's not the subject of my report.

Q. Okay.

A. And I guess I'll point out, since oxidative degradation risk was not assessed, I can't tell how Ethicon viewed that potential failure mode relative to the current state of the art.

Q. I meant to cover one more thing with you back there on page 44.

A. Yes, sir.

Q. Are you familiar with Section D.6.3, "Criteria for Risk/Benefit Judgments"?

A. Yes.

Q. Okay. Do you see where it says, quote, Those involved in making risk/benefit judgments have a responsibility to understand and take into account the technical, clinical, regulatory,

A. Not recently.
Q. Which ones did you read?
A. I can't tell you as I sit here today.
Q. I mean, you're aware that some of these folks had depositions of -- like up to six or seven different days? Are you aware of that?
A. Yes.
Q. And did you take any of these people and look at all their depositions?
MR. BOWMAN: Object to form.
THE WITNESS: I've looked at some depositions. I can't recall which ones exactly that I've looked at.
BY MR. DAVIS:
Q. Well, in connection with forming your opinions on whether or not Ethicon has support for its belief that oxidative degradation is not an issue, I mean, did you try to look at any depositions --
A. It is unnecessary. If it was considered, it will be in the FMEA. Bottom line. Doesn't matter who testified about it. They can say whatever they want to. If it's not in the FMEA, it was not considered.
Q. Okay. What if it's in the risk

analysis that is referenced in the FMEA? Does that mean they considered it or does it mean they did not consider it?

A. Are you talking about the device design safety assessment?

Q. I want to go back to Exhibit 10, yes.

A. Okay.

Q. Question Number 10 again.

A. You're talking about a question. You're not talking about an actual analysis. You're talking about a question.

Okay. Go ahead.

Q. You see it refers you to the Gynemesh PS design history file as support for their answer that they have considered the biocompatibility.

A. Yes.

Q. Okay. So, if that reference takes you to a risk assessment for the biocompatibility that includes oxidative degradation, then you would have to stand corrected?

A. No.

Q. Oh. Okay.

A. You don't have to go and fight through the weeds to figure out what's been done as an adequate safety analysis. I teach failure mode and

effects analysis. It will be listed on the document if it's considered.

Q. Are you telling the jury that ISO 14971 does not allow reference to other documents?

A. That's not what I said.

Q. Okay.

A. I said, if it's considered as a potential failure mode, it will be listed on the failure mode and effects analysis. And of course it references other documents. But, if it was considered as a potential failure mode, it will be listed on the FMEA.

Q. Can you explain --

A. There's no if, ands, or buts about it.

Q. Can you explain to the Court the meaning of the word "biocompatibility" as it relates to ISO 10993?

MR. BOWMAN: Object to form.

THE WITNESS: No. I will relate it to ISO 14971.

BY MR. DAVIS:

Q. Well, I'm not asking you about that ISO. I'm asking you about 10993. We'll talk about that one -- other one in a minute.

A. ISO 14971 references ISO 10993, and

Q. Have you ever prepared a -- or been on a team that was preparing an FMEA for a medical device?

A. No. No --

Q. Making it easier --

A. -- I've not been on a team. I've -- I've led teams on hundreds of FMEAs and -- and teach FMEAs, but I've not been on a particular team that's performing that for a medical device.

Q. But have you ever been on a team preparing a biocompatibility risk assessment under ISO 10993?

A. That's -- that's not my area of expertise.

Q. Okay. Do you know how to evaluate a biocompatibility risk assessment according to the -- to determine its compliance with the ISO 10993 standards?

A. That's not the subject of my report.

Q. Is that because in part it's beyond your expertise?

A. That is not my expertise -- I wouldn't say it's beyond my expertise; that's not my expertise.

Q. That's fair enough.

CERTIFICATE

STATE OF TENNESSEE)
COUNTY OF DAVIDSON)

I, Lise S. Matthews, RMR, CRR, CRC, LCR 353, Licensed Court Reporter and Notary Public, in and for the State of Tennessee, do hereby certify that the above deposition was reported by me, and the transcript is a true and accurate record to the best of my knowledge, skills, and ability.

I further certify that I am not related to nor an employee of counsel or any of the parties to the action, nor am I in any way financially interested in the outcome of this case.

I further certify that I am duly licensed by the Tennessee Board of Court Reporting as a Licensed Court Reporter as evidenced by the LCR number and expiration date following my name below. I further certify that this transcript is the work product of this court reporting agency and any unauthorized reproduction and/or transfer of it will be in violation of Tennessee Code Annotated 39-14-104, Theft of Services.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this _____ day of _____, 2016.

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Lise S. Matthews, RMR, CRR, CRC
LCR 353 Expiration Date 6/30/2016
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March 6, 2018